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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jeffrey E. FETTERMAN, et al. Confirmation No : 6372

Application No.: 10/722,262 : Group Art Unit: 3686

Filed: November 25, 2003 : Examiner: Rajiv J. Raj

Title: A METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED WITH A

PHARMACEUTICAL PRODUCT

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. §1.111

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Amendment and Response constitutes a complete and timely reply to the Office Action mailed December 2, 2008 in the above-identified application. The following remarks are respectfully submitted.

Amendments to the Claims begin on page 2.

Remarks begin on page 13.